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Examiner	:	T. Wessendorf
Group Art Unit	:	1627
Title	:	MIMOTOPES OF HYPERVARIABLE REGION 1 OF THE E2 GLYCO-PROTEIN OF HCV AND USEES THEREOF

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TRAVERSAL AND REQUEST FOR RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

A restriction requirement under 35 U.S.C. §121 was set forth in the Official Action dated June 4, 2001 in the above-identified patent application. It is the Examiner's position that claims 1-14, 17, 19-58, 60-62, 64-68, 70-78, 81-86 and 88-96 in the present application are drawn to five (5) patentably distinct inventions which are as follows:

Group I: Claims 1-14, 17, 19-31, drawn to library and method of use for screening epitopes of HRV1 of HCV;

Group II: Claims 32-57, drawn to a mixture of peptides obtained from a library;

Group III: Claims 58, 60-62 and 64-67, drawn to nucleic acid, host cell and method for producing a peptide;

Group IV: Claims 68, 70-78 and 81-83, drawn to a method of obtaining an antibody molecule;

and

Group V: Claims 84-86 and 88-96, drawn to antibody molecule and obtaining antibodies.

Applicants respectfully assert that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in § 1893.03(d) of the M.P.E.P.:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications...
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.... Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P.

In Example 17, it is clearly stated that there are corresponding special technical features between a protein and the DNA sequence encoding the protein, and therefore there is also unity of invention between them.

Moreover, it is noteworthy that, during the international stage of this application, in the International Search Report issued May 19, 1998, the Examiner did not make a a lack of unity finding and considered all of the claims to be directed to a single invention.

Plainly, the written restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under § 371.

Applicants intend to amend claim 32 such that it recites the subject matter, i.e., the library of peptides set out in claim 1. Such an amendment makes it abundantly clear that claim 32 is directed to a subset of peptides set out in claim 1. Clearly restriction between the peptides of Group I and the peptides of Group II is improper and is based on a distinction without a difference.

Finally, even if standard restriction practice were applicable in this case, it is improper to require restriction

between the peptides and nucleic acids disclosed in the present application, *i.e.*, between Groups II and III.

According to 35 U.S.C. 121, "If two or more **independent and distinct** inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [*Emphasis supplied.*] It is well established, however, that the sequence of nucleotides in a gene determines the order of the amino acids in the proteins encoded by the genes. According to M.P.E.P. § 802.01,

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are **unconnected** in design, operation, or effect...

[*Emphasis supplied.*] Since the order of the nucleotides in a gene and the order of amino acids in the corresponding protein are, in fact, intimately connected, the inventions of Groups II and III are not independent.

Therefore, even under restriction practice as it applies to applications filed under 35 U.S.C § 111(a), for example, restriction should not have been required between the claims directed to consensus amino acid sequences of HRV1 of HCV and nucleic acids encoding the same.

Plainly, the above-captioned restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under § 371. Moreover, the present requirement also fails to comply with established restriction practice as it applies to applications filed under 35 U.S.C § 111(a).

Additionally, as the Examiner correctly points out, this application is subject to PCT Rule 13. Rule 13.2 PCT (first sentence) states:

"Where a group of inventions is claimed in and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features."

Under Rule 13 of the PCT, the only criterion to be assessed is whether the groups of claims possess either the same or a corresponding special technical feature. As mentioned above, this inquiry must be answered in the affirmative. The presence of other features is irrelevant.

Rule 13.2 provides a definition of a "special technical feature":

"The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed invention, makes as a whole over the prior art."

The present invention relates to hypervariable region 1 (HRV1) variants of the E2 protein of hepatitis C virus (HCV) which are immunologically similar to a plurality of natural HVR1 variants and are therefore useful in inducing neutralizing antibodies against different HCV variants.

Groups I and II contain the special technical feature of a particular consensus amino acid sequence which is useful in inducing such antibodies. This consensus sequence reflects the contribution made by the claimed subject matter over the art.

Group III relates to nucleic acids which encode the amino acids of Group II. The contribution made by this subject matter over the art is the amino acid sequence which is encoded by the nucleic acid. This, therefore, represents a corresponding technical feature to that of Group II. Thus,

Groups II and III meet the requirements of Rule 13 PCT and should be examined together.

By the same reasoning, as mentioned above, Groups I and II also share a special technical feature. The peptides of Group II are members of the library of Group I, which is a more generic definition of the same invention. The special technical feature of the formula II amino acid sequence is a subset of the formula I amino acid sequences. The fact that one is a mixture, and one is a library is irrelevant to unity considerations and both groups of claims contain the same technical feature. Indeed, the Examiner has included Claim 31 in Group I, which states the formula II peptide claimed in claim 32.

In light of all the foregoing, Applicants respectfully traverse the restriction requirement and request that it be withdrawn upon reconsideration.

In order to be fully responsive to the above-mentioned requirement, Applicants hereby elect the subject matter of Group II for consideration in this application, with the understanding that Group II includes claims 32-57 drawn to a mixture of peptides obtained from a library. Applicants further elect Species A, Formula II or in composition form.

Claims 32-38 are readable on the elected species.

Applicants respectfully request that the Examiner confirm in writing, separately or as part of the next-issued Official Action, the gracious reconsideration of the written restriction requirement and the reconstitution of at least Groups I, II and III in compliance with international unity of invention practice as it applies to applications filed under § 371.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,

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